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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,873	09/05/2003	Shyam S. Mohapatra	USF-182XC1	6872

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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	PAPER NUMBER
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/655,873	MOHAPATRA ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9,11,12,14,15,18-21,23-31,43-50 and 52-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9, 11, 12, 14, 15, 18-21, 23-31, 43-50, 52-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Matters

1. This case has been transferred to a new examiner. The new examiner is Marcia Noble.

Status of Claims

2. Claims 1-4, 6-9, 11, 12, 14, 15, 18-21, 23-31, 43-50, and 52-68 are pending. Claims 1-4, 6-8, 43, 45-48, and 50 are amended, claims 5, 10, 13, 16, 17, 22, 32-42 and 51 are canceled, and claims 66-68 are newly added by amendment 11/13/2006. Claims 1-4, 6-9, 11, 12, 14, 15, 18-21, 23-31, 43-50 and 52-68 are under consideration.

Claim Objections

3. The objection of claims 46, 48 and 51, as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, is withdrawn.

Amended claims 46 and 48 still depend upon a rejected base, however the amendments to the claims 46 and 48 raise new grounds of rejection. Claim 51 was canceled and therefore its objection is rendered moot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The rejection of claims 1-4, 6-9, 11, 12, 14,15, 18, 19, 43-45,47,49,50,52, and 53, 59-65, under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. {Hogan et al. (1998) Eur. J. Immunol. 28: 413-423}, and further in view of Li et al. {Li. et al. (1996) J. Immunol. 157: 3216-3219} US patent 6,693,086 (2.17.2004) priority to (6.25.1998), hereafter referred to as Dow et al, and O'Donnell et al. {O'Donnell (1999) J. Immunol. 163:4246-4252}, is withdrawn.

Applicant amended these method claims to recite, "administering results in an increase of Th1-type cytokine production, an increase of IgG2a levels, a decrease of Th2-type cytokine production, and reduced serum IgE levels." The instant art does not

teach these specific limitations and as Applicant states in the remarks, filed 11/13/2006 (p. 11, par 2), there is not reasonable expectation that the outcome would be the above recited specific immune response. Therefore the rejection as it relates to claims 1-4, 6-9, 11, 12, 14,15, 18, 19, 43-45,47,49,50,52, and 53, 59-65 is withdrawn.

However, claims 20, 21, 23-31 and 54-58 stand rejected and new claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. {Hogan et al. (1998) Eur. J. Immunol. 28: 413-423}, and further in view of Li et al. {Li. et al. (1996) J. Immunol. 157: 3216-3219} and further in view of US patent 6,693,086 (2.17.2004) priority to (6.25.1998), hereafter referred to as Dow et al, and O'Donnell et al. {O'Donnell (1999) J. Immunol. 163:4246-4252}. The rejection is maintained for reasons of record set forth in the Non-Final Action, mailed 6/5/2006 at pages 4-6, which states the instantly cited art renders the claimed pharmaceutical composition comprising the IL12 vector, the IFN-gamma vector and an antigen obvious.

Claims 67 and 68 claim the pharmaceutical composition wherein said composition increases Th1-type cytokine production, increases IgG2a, decreases Th2-type production and reduces serum IGE *in vivo*.

In considering a product, such as the claimed composition comprising a IL-12 expression vector, an IFN-gamma vector and an antigen, its patentability **does not** depend upon the manner by which the product was produced or used (See MPEP 2113.). The claimed pharmaceutical composition of the instant invention is results increases Th1-type cytokine production, increases IgG2a, decreases Th2-type

production and reduces serum IGE when administered to a patient *in vivo*. If the same components of a composition are present, then composition should function in the same manner, even if it is not stated directly in the art that discloses the composition. Therefore, the means of use or effects of the composition does not carry patentable weight.

Applicant's arguments filed 11/13/2006 have been fully considered but they are not persuasive.

Applicant traverses this rejection on the grounds that one would not reasonable expect to receive the specific immune response claimed and that the benefits of the claimed method and compositions are unexpected and have a significant practical advantage for immunotherapy.

These arguments are not found persuasive because the instant claims are to a product and therefore as long as the same structural components are present the intended use and outcome from that use does not carry patentable weight. The art of record provides the IL-12 expression vector, the IFN-gamma vector, and an antigen, as well as a motivation to use these components together to elicit an immune response and treat 30-35% of the patients that fail to respond to BCG alone (see p 6, last paragraph of the Non-Final Rejection, mailed 6/5/2006). Therefore is would have been obvious at the time of filing to combined these components is a composition for treatment. Therefore, the rejection of claims 20, 21, 23-31 and 54-58 is maintained and extended to new claims 67 and 68.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

5. Claims 2-4, 6, 7, 8, 45-48, 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

The amended claims recite, "the administering step includes selecting". This recitation suggests that a selection step for obtaining IL-12 or IFN etc...occurs during administration. However, the specification does not teach any means of selection during the administration step. Therefore, the specification provides no literal or figurative support for this recitation.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 2-4, 6, 7, 8, 45-48, 50 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Because most gene therapy methods that administer a vector do not have a selection step in the process, an artisan would not know what type of selection is necessary and therefore would not know how to use or make the instant method with the claimed administering step includes a selection.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure" (emphasis added).

Scope of Enablement

6. Claims 1-4, 6-9, 11, 12, 14, 15, 18-21, 23-31, 43-50, and 52-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification,

while being enabling for:

A method of modulating an immune response comprising administering by intramuscular injection to a patient an effective amount of pharmaceutical composition comprising a nucleic acid encoding the nucleic acid sequence of SEQ ID NO:7, which encodes the p35 subunit of human IL-12, and the nucleic acid sequence of SEQ ID NO:9, which encodes the p40 subunit of human IL-12 both operably linked to a promoter capable of driving expression of said nucleic acid and the nucleic acid sequence of SEQ ID NO:11, which encodes human IFN-γ, operably linked to a promoter capable of driving expression of said nucleic acid, and administering an antigen subcutaneously, wherein the administration of said composition and said antigen results in an increase of Th1-type cytokines INF-γ and IL-2, an increase in the levels of IGg2a specific to said antigen, a decrease of Th2-type cytokine IL-2, and reduced serum IgE levels;

And while being enabled for:

A pharmaceutical composition comprising a nucleic acid encoding the nucleic acid sequence of SEQ ID NO:7, which encodes the p35 subunit of human IL-12, and the nucleic acid sequence of SEQ ID NO:9, which encodes the p40 subunit of human IL-12 both operably linked to a promoter capable of driving expression of said nucleic

acid and the nucleic acid sequence of SEQ ID NO:11, which encodes human IFN-γ, operably linked to a promoter capable of driving expression of said nucleic acid,

does not reasonably provide enablement for:

A method comprising administering 1) any nucleic acid sequence encoding IL-12, a promoter operably linked to any nucleic acid or protein, any nucleic acid sequence encoding any IFN-γ, a promoter operably linked to any nucleic acid or protein, and an antigen, 2) administering by any route of administration, 3) administering the two nucleic acids independently, wherein the administering step involves a selection step, 4) and wherein the administration results in an increase in any or all Th1-type cytokine production, an increase in any or all IgG2a, a decrease in any or all Th2-type cytokine production, and a decrease in IgE levels;

and does not reasonably provide enablement for:

A pharmaceutical composition comprising any nucleic acid sequence encoding IL-12, a promoter operably linked to any nucleic acid or protein, any nucleic acid sequence encoding any IFN-γ, a promoter operably linked to any nucleic acid or protein, and an antigen.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make or use the claimed invention, if

not, whether an artisan would require undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue".

Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The specification discloses a method of vaccinating with a mixture of pIL12 and pIFN-γ, and a crude KGB extract (p. 21-22, bridging par). The specification teaches the construction of a composition that comprises a mixture of two plasmids. The first is a plasmid vector encoding the p35 and p40 subunits of IL-12 operably linked to the CMV promoter. The second is a plasmid vector encoding human IFN-γ operably linked to the CMV promoter (p. 22). The specification teaches a method of vaccinating mice wherein naïve mice are treated with a series of intramuscular injections of the plasmid vectors in a mixture, along with a subcutaneous injection of a crude KGB extract (p. 21-22, bridging par). The specification teaches the treatment with the pIL12 and IFN-γ mixture

resulted in a significant decrease in IgE levels and a significant increase in IgG2a specific for the administered antigen compared to sole treatment with either plasmid (p. 25, example 2 and p. 28, last par). The specification teaches that the administration of said plasmid mixture results in increase the Th1-type cytokines, IL-2 and IFN-γ, and a decrease in the Th2-type cytokine, IL-4 and that these expression profiles of Th1-type cytokines and TH2-type cytokines serve as specific markers of the effectiveness of a vaccine (p. 29, par 1).

However the specification does not enable the instant invention for the full breadth of the claims for the following reasons:

1) The instant claims are drawn to a gene therapy for vaccination using a genetic adjuvant that requires the successful expression of two expression vectors. However, the claims encompass a) an expression vector that is not operable and b) also encodes any sequence of the p40 and p35 subunits of IL-12.

a) The instant claims recite a nucleic acid sequence and an operably linked promoter (see claims 1, 20, 43, and 54). As written, the claims do not require that the promoter be operably linked to the gene of interest. Nucleic acid sequences of the instant claims can be linked to and operable with any gene. Therefore, essentially the claims encompass the administration of a vector that contains coding sequences that do not have an operably linked promoter to drive the expression of the gene of interest, IL-12 and IFN-gamma. In narrowing embodiments the claims are drawn to the p35 and p40 subunits being operably linked to a promoter. However, for promoters to drive expression of an expression vector they must be linked to coding sequences of gene,

not protein sequences as is encompassed by the claims. An expression vector minimally requires a coding sequence of a gene of interest and a promoter to drive gene expression of said coding sequence. Therefore an artisan would not know how to use or make the instant method or composition with vectors that comprise a coding sequence and a promoter operably linked to some of gene or linked to a protein sequence as encompassed by the claims.

b) The instant invention is drawn to an expression vector encoding "an amino acid sequence of" (such as claim 3 and 50) which encompasses any sequence encoding said amino acids, including fragments thereof. This will encompass a non-coding segments or short fragments of the amino acid sequence that do not have biological activity of IL12 or IFN-γ and therefore would not result in the Ig and cytokine expression profile claimed. Furthermore, the specification only teaches the use of the full coding sequences of the p35 and p40 subunits of IL-12 or SEQ ID NOS:7 & 9 and the full IFN-γ gene sequence of SEQ ID NO:11, which comprise whatever biological active components necessary to obtain the claimed immune response. Because the specification does not disclose which fragments of these sequences are encoding the biologically active and functioning components of the sequences, an artisan would only know how to use or make the instant method and composition to obtain the claimed immune response using the full sequences disclosed.

2) The instant claims are drawn to a gene therapy vaccination method that is delivered by any route administration. The general art of gene therapy and DNA vaccination is unpredictable. Van Drunen Little-van den Hurk et al (Immuno Rev

199:113-125, 2004) teach that, "there is not one DNA vaccine that has been approved for either human or veterinary use. This lack is mainly due to their relatively low efficiency [p. 114, par bridging col 1 and 2]." Among the few effective DNA vaccination approaches, the route of immunization has been found to be an important determinant of immunogenicity and that the most effective means have been by localized routes of administration and intramuscular administration (Scheerlinck Vaccine 19:2647-2656, 2001). However, other arts suggest a great degree of unpredictability in delivery of a gene by different routes of administration. Gautam et al (Am J Respir Med, 1(1) abstract) discloses the use of different vector delivery routes to the lung, such as intravenous injection, intratracheal installation, and aerosol with varying degrees of success. They further disclose various barriers to delivery of vectors such as serum proteins during intravenous injection, surfactant and mucus interference during more topical applications of vectors. There have also been the problem of immune and cytokine responses against the vector delivery vehicle obstructing delivery of gene therapies. Yang discloses barriers to the use of various catheters in gene delivery during vascular gene therapy stating low transfection efficiency, high prevalence of tissue injury, and poor control of delivery to the cells of targeted vessels (Radiology, 228(1) p. 38 col 1 lines 1and 2, p 39 col 1 lines 22-31 and lines 50-55, 2003). Because many problems are associated with the modes of delivering a vector for gene expression and immunization, the art demonstrates that route of administration is unpredictable.

The breadth of the instant invention is drawn to delivering an expression vector by any means. However, as disclosed above, route of administration is a highly unpredictable factor and therefore, an artisan would look to the specification for specific guidance to overcome the unpredictabilities in the art. However, the specification only provides specific guidance on how to effective produce an immune response as claimed by intramuscular administration of the plasmids followed by subcutaneous injection of an antigen. Therefore, an artisan would only know how to predictably use/make the instant invention by administering the vectors by intramuscular administration and subcutaneous injection of the antigen.

3) The breadth of the instant claims encompass a method of delivering the two expression vectors separately at different time periods. However, the specification teaches that the method is not effective to the IL-12 and IFN-γ are delivered independently (p. 28 and 29). Furthermore, the specification teaches that the vectors are delivered as a mixture (p. 21-22, bridging par). Therefore, the specification only supports delivering a composition comprising a mixture of the two vectors. Again, because the method claims a specific immune response and it is not clear the exact parameters that are eliciting the immune response, an artisan would only know how the produce the claimed immune response by replicated the method disclosed in the specification. Therefore, the artisan would only know how to use or make the instant invention by delivering a mixture of the IL-12 and IFN-γ vectors as taught in the specification.

4) The claims are broadly drawn to eliciting an immune response comprising an increase in Th-1 type cytokine, an decrease in Th-2 type cytokine production, an increase in any or all IgG2a, and a decrease in serum IgE. However, the Th1 and Th2 type cytokines are genera of cytokines that have several known species members. However, the specification only discloses the use of IL-2 and INF-γ as examples of Th1 type cytokines and IL-4 as an example of Th1 cytokines. Because the novelty of the instant invention seems to be in the specific type of immune response being elicited, it is not clear that the expression profiles of one or two cytokines from each group would represent the full breadth of Th1-type cytokine production and th2-type cytokine production. Therefore, because the other cytokines of the genera were not measured an artisan would not know if other Th1 and Th2 type cytokine expression profiles will be indicative of the claimed immune response. Therefore, because the specification only discloses IL-2, IFN-γ, and IL-4 expression profiles, the invention is only enabled for these specific cytokines.

Similarly, the claims are drawn to the immune response comprising increased IgG2a, however, the intent of the instant method is for the expression of the IL12 and the IFN-γ expression vector to serve as an adjuvant to enhance the immune response to an antigen. Therefore, the invention necessitates specifically that it increase IgG2a that are specific for the antigen that was co-administered. Otherwise it would be unclear how to use or make the instant invention for its intended use as a genetic adjuvant and therefore, the instant invention is only enabled for IgG2a that are specific for the antigen of interest.

Therefore, due to the lack of specific guidance taught by the specification and the unpredictability of the gene therapy/DNA vaccination art, the instant invention is not enabled for the full breadth of the claims.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4, 6-9, 11, 12, 14, 15, 18-21, 23-31, 43-50, and 52-68 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 20, 43, and 54 recite, "and an operably linked promoter sequence". The metes and bounds of this recitation are indefinite because it is not clear to what the promoter is linked. Claims 2-4, 6-9, 11, 12, 14, 15, 18, 19 , 21, 23-31, 44-50, 52, 53, and 55-68 depend from claims 1, 20, 43, and 54, which have been deemed indefinite, therefore, these dependent claims are rendered indefinite.

Claims 3, 4, 23, 24, 50, and 57 recite "IL-12 to comprise" a protein sequence. However, the base claims from which these claims depend are drawn to a nucleic acid. Therefore, it is not clear if the instant invention is supposed to administer a nucleic acid encoding the p35 and p40 subunit of IL-12 only or if the administration is a combination of a nucleic acid encoding IL-12 and IL-12 protein.

Claim 2 recites "selecting the IL-12 to be human IL-12 and the IFN-gamma is human IFN-gamma". The metes and bounds of this recitation are indefinite because it is not clear if the IFN-gamma is intended to be part of the selection step.

Claim 4 recites, "wherein the p35 subunit is being operably linked to a promoter sequence and the p40 subunit being operably linked to a promoter sequence". P35 and p40 subunits are polypeptides and therefore it unclear what the purpose of linking them to a nucleic acid promoter sequence would be. Furthermore, this would not be operable, as the claim encompasses.

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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